25. A method of performing simultaneous forward and reverse ABO type, comprising:

(a) reacting a sample of blood with anti-A and anti-B antibodies wherein the antibodies are bound to a detectable label;

(b) reacting a sample of blood with reagent red blood cells bearing labeled A antigen and labeled B antigen;

(c) subjecting the sample to visual or spectrophotometric analysis; and

(d) analyzing the visual or spectrophotometric analysis to determine ABO type;

wherein the visual analysis comprises column agglutination technology.

A4

26. The method of claim 25 wherein the reagent red blood cells of step (b) are stained.

27. The method of claim 26 wherein the column agglutination technology is a column agglutination test reaction and separation vessel in cassette form.

28. The method of Claim 27 wherein an automated computerized imaging system is employed to interpret an agglutination result.

REMARKS

Claims 1-24 are pending in the application and have been rejected. After this Amendment, claims 16, 20, 22-23 and new claims 25-28 are in this case. It is respectfully submitted that the amended claims as well as the newly added claims are fully supported in the specification as filed and that no new matter has been added.

The amendments have been made pursuant to the requirements of Rule 121 of the Rules of Practice. Specifically, the pending claims are written above in clean form and in accordance with 37 C.F.R. § 1.121(c)(1)(i) and § 1.121(c)(3). Pursuant to the requirements of 37 C.F.R.§ 1.121(c)(1)(ii), another version of the amended claims is attached hereto as Exhibit A. This Exhibit A version has been marked up to show all changes made in this amendment relative to the previous version of each claim. As stated hereinabove, the amendments do not constitute new matter. Entry and consideration of the amendments is therefore respectfully requested.

Informal Drawings

The Examiner has noted that the application has been filed with informal drawings which are acceptable for examination purposes only and that formal drawings will be required when the application is allowed. Applicants acknowledge this requirement and will forward formals when allowable subject matter is indicated.

Specification

The Examiner has pointed out the typographical error at page 3 line 28. Applicants have herein made the correction required.

Rejection under 35 U.S.C. §112

The specification was objected to under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the

invention, i.e. failing to provide an enabling disclosure. In particular, claims 1-24 were rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner avers that Applicant desires simultaneous determination of forward and reverse ABO blood group, and that this is exemplified by reacting a blood sample with differently labeled anti-A antibodies and B-bearing cells, or with differently labeled anti-B antibodies and A-bearing cells. The Examiner further avers that absent further description and guidance from Applicant, one would not be able to make and use the invention as instantly claimed in which all of anti-A antibodies, A-bearing cells, anti-B antibodies, and B-bearing cells are reacted with the same sample because all samples tested would have a reaction between the specific binding pairs A/anti-A and B/anti-B. Moreover, the Examiner states that reacting different sample fractions with the combination of anti-A antibodies and anti-B antibodies (forward), or with the combination of A-bearing cells and B-bearing cells (reverse) does not allow one to accomplish simultaneous determination of forward and reverse ABO blood group as desired.

Applicants respectfully traverse this rejection. Applicants have provided working examples of the simultaneous determination. With reference to the Examples, Applicants respectfully show the methods for undertaking such an analysis. More specifically, and with respect to the claims currently in the case, Applicants draw the Examiners attention to Example 2 Part

C appearing at page 31, lines 8-19. The results thereof are shown in Table 6.

The Examiner further avers that claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the Examiner avers that Applicant teaches the use of labeled reagent red cells bearing antigens (see e.g., page 6, lines 14-15, and page 10, lines 22-28) and does not teach cells bearing labeled antigens as is instantly claimed, and that, absent further description from Applicant, one would not be guided to, and would not be assured of the ability to, label the antigens with the labels as instantly disclosed and claimed. Moreover, the Examiner avers, Applicant provides no guidance to fluorochromes as antigen as instantly recited in claim 7.

Without acquiescing in this rejection, Applicants respectfully submit that this rejection has been made moot by Applicants' cancellation of claims 1-15. Therefore, Applicants respectfully request that this rejection be withdrawn.

Claims 1-2, 4-7, 11-12, 14-17 and 19-24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant

regards as the invention. In particular, the Examiner avers that in claims 1-2, 4-7, 14-17, and 19-24, the interrelationships of the sample or samples are not clear. More specifically, the Examiner avers that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. The Examiner notes also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). The Examiner further avers that in the present instance, claims 6 and 7 recite the broad recitation "phycobiliproteins", and these claims also recite "including phycoerythrin" which is the narrower statement of the range/limitation; and, claims 11-12 recite the broad recitations "reactive dyes", "lipophilic dyes", or "monoclonal antibodies", and these claims also recite "e.g., fluorescein...", "e.g., merocyanine...", or "e.g., anti-glycophorin-PE..." which are, respectively, the narrower statements of the range/limitation; in claims 6-7, the abbreviations "FITC", "BODIPY", "AMCA", and "TRITC" should be defined for clarity. It is not clear for what the indocarbocyanine is "reactive" and,

thus, it is not clear what is encompassed; in claims 11-12, the abbreviations "PE" and "DiIC1$(3)-DS" should be defined for clarity. The Examiner avers it is not clear for what the lipophilic dyes are "reactive" and, thus, it is not clear what is encompassed; in these claims, "the reactivity" lacks antecedent basis.

Without acquiescing in the rejection, Applicants respectfully submit that this rejection has been made moot as to claims 1-2, 4-7, 11-12, 14-15, 17 and 19 by Applicants' cancellation of claims 1-2, 4-7, 11-12, 14-15, 17 and 19. Applicants respectfully request that this rejection be withdrawn as to those claims. Applicants traverse the rejection with regard to claims 16 and 20, as it is unclear to Applicants how this rejection might apply. That is, Applicants see no potentially inconsistent range of limitation in claims 16 and 20. The Examiner has offered no specific information as to the reason for the rejection of these claims. Applicants respectfully request that the Examiner provide more specific information or alternatively, withdraw the rejection as to claims 16 and 20.

The Examiner avers that claims 22-24 contain the trademark/trade name BIOVUE™; and that where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph, referencing Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982); the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product; that a trademark or trade name is used to identify a source of goods, and not the goods themselves,

thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a cassette of unknown structure/limitation containing columns with added microparticle matrix for column agglutination and, accordingly, the identification/description is indefinite.

In claims 23-24, the Examiner avers it is not clear how the system or reader are related to or further limit "visual analysis".

Claim 23 contains the trademark/trade name AUTOVUE™. The Examiner avers that where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph, referencing Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982); the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product, that a trademark or trade name is used to identify a source of goods, and not the goods themselves and thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the Examiner avers the trademark/trade name is used to identify/describe an automated reader/imaging system of unknown structure/limitation and, accordingly, the identification/description is indefinite; further, the recitations of "the ... system" and "the agglutination result" lack antecedent basis.

Claim 24 contains the trademark/trade name BIOVUE™ Reader 2. The Examiner avers that where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph, referencing Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982), further stating that the claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. The Examiner avers that a trademark or trade name is used to identify a source of goods, and not the goods themselves, and thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the Examiner avers that the trademark/trade name is used to identify/describe an automated reader/imaging system of unknown structure/limitation and, accordingly, the identification/description is indefinite. Further, it is averred, the recitations of "the ... Reader 2" and "the agglutination result" lack antecedent basis.

Claim 24 has been canceled. Applicants have amended claim 22 to delete reference to the BioVue™ cassette but rather claim it generically. Applicants respectfully submit that the amendment is fully supported by the specification as filed in that the BioVue™ cassette is described in the specification at page 8 line 26- page 9 line 3, and page 13 line 29 - page 14 line 1. Further amendment has been made to claim 23 to provide antecedent basis; e.g., "the Ortho AutoVue™ System" has been deleted entirely and replaced with "an automated computerized imaging system" and "the agglutination result" is now amended to state "a result". Support for the term "an

automated computerized imaging system" in claim 23 is found in the specification at page 9 lines 5-16 and page 14 lines 2-3.

Regarding the Examiner's query in claim 23-24 as to how the system or reader are related to or further limit "visual analysis", Applicants make reference to amended claim 16 wherein the limitation of "column agglutination technology" has been added to "visual analysis", and further wherein the specification states that the column agglutination cassette and CAT technology allow visual detection. See specification at pages 22-25 and in particular at page 22 lines 4-14. Two visual methods are commonly used by those evaluating a CAT sample: visual evaluation by a technician of a band of agglutinated cells, or via an automated computerized imaging system or "reader" which evaluates presence or absence of agglutination.

Rejection Under 35 USC 102(b)

Claims 1-11 and 14-20 were rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ullman (U.S. Pat. No. 4,584,277). The Examiner avers Ullman teaches fluorescently labeled anti-blood group antigen antibodies and fluorescently labeled erythrocytes having blood group antigens thereon added simultaneously or sequentially to a sample of whole blood for multiparameter analysis of ABO blood type and isoantibodies (i.e. reverse blood typing) (see e.g. col. 3-4). A variety of combinations of parameters and suitable reagents are taught (see e.g. col. 3, Table 1). Suitable fluorescent labels are taught (e.g. col. 8-9); inherently, antibodies of the ABO system are generally IgM.

Applicants have canceled claims 1-11, 14-15 and 17-19 and respectfully submit that this rejection has thereby been rendered moot as to those claims. Applicants traverse this rejection as it applies to claims 16 and 20; Applicants have amended claim 16 to limit the methods therein to "visual or spectrophotometric analysis", and wherein the visual analysis comprises column agglutination technology. There is no disclosure in Ullman teaching use of visual or spectrophotometric detection, the Ullman disclosure being directed to fluorescent detection. Claim 20, depending as it does on amended claim 16, and claiming that the reagent red blood cells are stained for said column agglutination technology, is similarly neither taught nor suggested in Ullman. For these reasons, Applicants respectfully submit that claims 16 as amended and 20 are patentable over Ullman.

Claims 16, 17, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yves [Lapierre] et al. (U.S. Pat. No. 5,338,689). The Examiner avers that LaPierre et al. teaches a column agglutination assay and device for determination of agglutinated reactants, especially red blood cells in forward and reverse blood typing assays (see e.g. Figs. 5-7). The Examiner avers that the blood typing assays require the addition and reaction of reagents as instantly claimed (see e.g. col. 4-6). The reference teaches that the solid carrier particles, e.g. erythrocytes, can be naturally colored or can be stained or labeled (see e.g. col. 2).

Cross-hatched for color

Applicants have canceled claims 17, 19, 21 and 24. However, as to claims 16, 20 and 22-23, Applicants

traverse the rejection for the following reasons. Applicants respectfully submit that nothing in LaPierre teaches the claimed *simultaneous* forward and reverse blood typing. Nothing in LaPierre teaches or suggests use of Applicants' methods of treating a population of reagent red blood cells with a dye in order to alter the color of one reagent cell population with respect to the other. In Applicants' visual and spectrophotometric analysis methods, Applicants teach treatment of one population of reagent red blood cells with sodium azide or cyanide (thereby turning the red color to brown). After agglutination in accordance with the methods of the invention, the brown agglutinates are discriminated from the red agglutinates either visually or spectrophotometrically (e.g., by absorbance or reflectance). See specification at page 22 lines 4-14, and page 31 lines 5-17, Table 6 and Figure 6, wherein it is shown that agglutinated cells of one color (e.g., brown) are distinguishable from unagglutinated cells of another color (e.g., red).

Applicants therefore respectfully submit that since nothing in LaPierre teaches or suggests such *discrimination of two distinct cell populations in a single column*, the instant claims are patentable thereover and the rejection should be withdrawn.

Claims 16, 17, and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chachowski et al. (U.S. Pat. No. 5,552,064). The Examiner avers Chachowski et al. teach a column agglutination assay and device (see e.g. col. 4-5) for determination of agglutinated reactants, especially red blood cells in forward and

reverse blood typing assays (see e.g. col. 6-8). The Examiner further avers that inherently the blood typing assays require the addition and reaction of reagents as instantly claimed and that the reference teaches that erythrocytes are naturally stained by their hemoglobin content (see e.g. col. 7).

Applicants traverse this rejection in that nothing in Chachowski et al. teaches *simultaneous* forward and reverse blood typing as claimed. Nothing in Chachowski et al. teaches or suggests use of Applicants' methods of treating a population of reagent red blood cells with dye in order to alter the color of that one population with respect to the other. In Applicants' visual and spectrophotometric analysis methods, Applicants teach treatment of one population of reagent red blood cells with sodium azide or cyanide (thereby turning the red color to brown). After agglutination in accordance with the methods of the invention, the brown agglutinates are discriminated from the red agglutinates either visually or spectrophotometrically (e.g., by absorbance or reflectance). See specification at page 22 lines 4-14, and page 31 lines 5-17, Table 6 and Figure 6, wherein it is shown that agglutinated cells of one color (e.g., brown) are distinguishable from unagglutinated cells of another color (e.g., red).

Applicants therefore respectfully submit that since nothing in Chachowski et al. teaches or suggests such *discrimination of two distinct cell populations in a single column*, the instant claims are patentable thereover and the rejection should be withdrawn.

The Examiner notes that this application currently names joint inventors and that in considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary; Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103. Applicants acknowledge the forgoing obligation and confirm that the subject matter of the various claims was commonly owned at the time the inventions covered therein were made.

Claims 1-12 and 14-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ullman (U.S. Pat. No. 4,584,277) in view of Vorpahl et al (U.S. Pat. No. 5,071,774) and Chang et al (U.S. Pat. No. 4,748,129). The Examiner avers that the teachings of Ullman are as set forth above and differ from the invention as instantly disclosed in not teaching agglutination of the erythrocytes and in not teaching fluorophore incorporated into the erythrocytes. In particular, the Examiner avers that Vorpahl et al. teach that determination of the agglutination of two sets of red blood cells can be used for determination of the presence of an agglutinating agent for one or both of the red blood cell sets (see e.g. col. 9); that as in Ullman, combined addition of means for separately agglutinating two sets of red blood cells (e.g., anti-blood group antigen antibodies) along with the two sets of erythrocytes (e.g. erythrocytes

having blood group antigens thereon), at least one of the sets being labeled with a fluorophore such that the sets are separately detectable and distinguishable, to a sample is used in the method.

The Examiner further avers Chang et al. teach the addition of a fluorescent agent capable of incorporation into a cell as a means of labeling erythrocytes for agglutination assays, and that suitable fluorescent agents are taught (e.g. col. 4-7).

The Examiner avers it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used agglutinating anti-blood group antigen antibodies, as in Vorpahl et al, in the method of Ullman because one would have expected such antibodies to perform their expected and desired binding function in the assay of Ullman, as modified, and would not have expected such agglutinating antibodies to interfere in the determination because Vorpahl et al. teach that agglutination is desirable and detectable with a method of like design; that it would have been further obvious to have used a fluorescent agent capable of incorporation into a cell, as in Chang et al., as the means of labeling erythrocytes in Ullman because Ullman requires fluorescently labeled erythrocytes, Chang et al teach incorporated labeling as particularly useful in assays typing red blood cells, and one would have expected the incorporated labeling to function as desired for providing fluorescently labeled cells in Ullman, as modified. The use of any known and available fluorescent agent capable of incorporation into a cell having the properties preferred by Chang et al would have been an obvious substitution to one of ordinary skill in the art.

It would have been further obvious, the Examiner avers, to formulate the reagents of Ullman, as modified, into a kit since that is conventional for convenience, economy, and reproducibility.

Applicants have canceled claims 1-12, 14-15, and 17-19, thus this rejection has been rendered moot as to those claims. Applicants traverse this rejection with regard to claims 16 and 20. Applicants respectfully submit that in view of the amendment to claim 16 requiring visual or spectrophotometric analysis of the agglutinates, nothing in Ullman when combined with Vorpahl and Chang render these claims unpatentable, as each of Ullman, Vorpahl and Chang are directed to labeling of cells with fluorochromes, and detecting result using fluorescent spectroscopy. In further contrast, Applicants' claimed methods are directed to simultaneous use of two populations of reagent red blood cells, one population of which are stained. After agglutination in accordance with the methods of the invention, the agglutinates of one color are discriminated from the unagglutinated cells of the other color either visually or spectrophotometrically (e.g., by absorbance or reflectance). See specification at page 22 lines 4-14, and page 31 lines 5-17, Table 6 and Figure 6, wherein it is shown that agglutinated cells of one color (e.g., brown) are distinguishable from unagglutinated cells of another color (e.g., red).

Applicants therefore respectfully submit that since nothing in Ullman when combined with Vorpahl et al. and Chang et al. teach or suggest the *discrimination of two distinct cell populations in a single column*, the instant

claims are patentable thereover and the rejection should be withdrawn.

Claims 16, 17, and 19-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chachowski et al (U.S. Pat. No. 5,552,064) in view of Shen et al (U.S. Pat. No. 5,594,808). The Examiner avers that the teachings of Chachowski et al. are as set forth previously in this Office action and differ from the invention as instantly claimed in not teaching an apparatus for interpretation of agglutination results; that Shen et al. teach an apparatus and method for classifying agglutination reactions in column agglutination devices; and that it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have used the device of Shen et al for interpreting the results of Chachowski et al. because of the express suggestion in Shen et al. to do so. The Examiner thus concludes that the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicants have canceled claims 17, 19, 21 and 24, thus rendering this rejection moot as to those claims. Applicants traverse this rejection as to claims 16, 20, and 22-23. Applicants respectfully submit that nothing in Chachowski et al. either alone or when combined with or Shen et al. teach the claimed *simultaneous* forward and reverse blood typing. Chachowski et al. is directed to use of column agglutination technology (CAT) to detect presence of binding ligands, for example, blood group antigens or antibodies thereto, using separate forward and reverse or crosscheck tests, further employing a separation matrix. Shen et al. is directed to an

automated computerized imaging system that is used to detect optically detectable binding complexes for example, carrier-bound antigens or antibody complexes and non-complexed carrier-bound antibodies and antigens, that form an agglutination pattern in microreaction vessels such as those used for column agglutination technology (CAT).

Nothing in Chachowski et al. or Shen et al. either teaches or suggests, nor would the teachings either alone or when combined motivate one to Applicants' methods of treating a population of reagent red blood cells with dye in order to alter the color of one population with respect to the other. In Applicants' visual and spectrophotometric analysis methods, Applicants teach treatment of one population of reagent red blood cells with sodium azide or cyanide (thereby turning the red color to brown). After agglutination in accordance with the methods of the invention, the brown agglutinates are discriminated from the red agglutinates either visually or spectrophotometrically (e.g., by absorbance or reflectance). See specification at page 22 lines 4-14, and page 31 lines 5-17, Table 6 and Figure 6, wherein it is shown that agglutinated cells of one color (e.g., brown) are distinguishable from unagglutinated cells of another color (e.g., red).

Applicants therefore respectfully submit that since nothing in Chachowski et al. when combined with Shen et al. teaches such *discrimination of two distinct cell populations in a single column*, the instant claims are patentable thereover and the rejection should be withdrawn.

For the above-stated reasons and in light of Applicants' amendments made herein, it is respectfully submitted that the claims are patentable over the art cited. Applicants therefore request that the rejections be withdrawn and the claims be allowed.

Please charge the fees due in connection with the filing of this amendment to Deposit Account No.10-0750/CDS-221/CKG in the name of Johnson & Johnson.

Respectfully submitted,

Catherine Kurtz Gowen
Attorney for Applicants
Registration No. 32,148

DATE: August 3, 2001

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Telephone No. 732-524-2681
Facsimile No. 732-524-2808

EXHIBIT A

Please cancel claims 1-15, 17-19, 21, and 24.

Please amend claim 16 as follows:

16. (Amended) A method of analyzing blood, comprising:

(a) reacting a sample of blood with anti-A and anti-B antibodies;

(b) reacting a sample of blood with reagent red blood cells bearing A antigen and with reagent red blood cells bearing B antigen;

(c) subjecting the sample to visual or spectrophotometric analysis; and

(d) analyzing the visual or spectrophotometric analysis to determine ABO type; wherein the visual analysis comprises column agglutination technology.

Please amend claim 22 as follows:

22. The method of claim [21] 20 wherein the column agglutination technology is a column agglutination test reaction and separation vessel in cassette form.

Please amend claim 23 as follows:

23. The method of Claim 22 wherein [the Ortho AutoVue™ System] an automated computerized imaging system is employed to interpret [the] an agglutination result.

Please add new claims 25-28 as follows:

-- 25. (New) A method of performing simultaneous forward and reverse ABO type, comprising:

(a) reacting a sample of blood with anti-A and anti-B antibodies wherein the antibodies are bound to a detectable label;

(b) reacting a sample of blood with reagent red blood cells bearing labeled A antigen and labeled B antigen;

(c) subjecting the sample to visual or spectrophotometric analysis; and

(d) analyzing the visual or spectrophotometric analysis to determine ABO type;

wherein the visual analysis comprises column agglutination technology.

26. (New) The method of claim 25 wherein the reagent red blood cells of step (b) are stained.

27. (New) The method of claim 26 wherein the column agglutination technology is a column agglutination test reaction and separation vessel in cassette form.

28. (New) The method of claim 27 wherein an automated computerized imaging system is employed to interpret an agglutination result. --